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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/454,651	12/06/1999	PETER S. LINSLEY	30436.30USD1	4031

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EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/454651

Applicant(s)

LINSLEY

Examiner

GAMBEL

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/24/02; 9/2/02
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38, 40, 43-45 is/are pending in the application.
- 4a) Of the above claim(s) 38, 40, 43-45 is/are withdrawn from consideration:
- 5) ☐ Claim(s) 38, 40, 43-45 is/are allowed.
- 6) ☒ Claim(s) 38, 40, 43-45 is/are rejected.
- 7) ☐ Claim(s) 38, 40, 43-45 is/are objected to.
- 8) ☐ Claim(s) 38, 40, 43-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/24/02 are: a) ☐ accepted or b) ☐ objected to by the Examiner. SEE PAPER NO 22
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on 11/24/02 is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☒ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u> </u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u> </u> | 6) <input type="checkbox"/> Other: <u> </u> |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/24/02 has been entered.

Applicant's amendment, filed 9/20/02 (Paper No. 20), have been entered.
Claims 40 and 44 have been amended.
Claim 45 has been added.

Claims 38, 40 and 43-45 are pending and being acted upon.

Claims 1-37, 39, 41 and 42 have been canceled previously.

2. The rejections of record can be found in the previous Office Action (Paper No. 13).
3. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 22.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

4. As noted previously; in view of applicant's Petition to Correct Inventorship Under 37 CFR 1.48(b)(c), filed 6/18/00; the inventorship in this nonprovisional application has been changed by the deletion of Philip Wallace and Nitin Damle and by the addition of Robert Peach and Jurgen Bajorath have been added.

The current inventors include Linsley, Ledbetter, Bajorath, Peach and Brady.

Applicant is requested to verify the inventorship of the instant application, given that the inventorship of the priority documents appear to differ from the inventorship currently indicated.

Therefore, applicant's Petition to Correct Inventorship Under 37 CFR 1.48(b), filed 9/30/02, reiterates that the inventorship in this nonprovisional application has been changed by the deletion of Philip Wallace.

Now, applicant's amendment, filed 9/20/02 (Paper No. 20), asserts that Linsley, Ledbetter, Damle and Brady are the inventors of the pending claims.

However, Damle has been deleted previously as an inventor.

Bajorath and Peach have been added as inventors.

Therefore, applicant has created an ambiguity as to the inventorship of the instant claims.

Further, the current inventorship of Linsley, Ledbetter, Bajorath, Peach and Brady differs from the prior art.

Applicant is required to verify and clarify the inventorship of the instant claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

6. Claims 38, 40 and 43-45 are rejected under 35 U.S.C. § 102(e) as being anticipated by Linsley et.al. (U.S. Patent No. 5,580,756) essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 13/18/22).

Applicant's arguments, filed 9/20/02 (Paper No. 20), have been fully considered but are not found convincing essentially for the reasons of record and addressed above.

While applicant's amendment, filed 9/20/02 (Paper No. 20), asserts that Linsley, Ledbetter, Damle and Brady are the inventors of the pending claims, it is noted that the current inventorship of the instant application is Linsley, Ledbetter, Bajorath, Peach and Brady, which differs from the prior art.

Therefore, invention was described in a patent by another, in contrast to applicant's assertions.

The following is reiterated for applicant's convenience.

Linsley et al. teach the use of B7 and B7 fusion proteins to inhibit neoplasia (see entire document, including Summary of the Invention, Detailed Description of the Invention such as columns 5-11 and Uses In Vitro and In Vivo, particularly columns 12-13).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced B7 molecules to regulate CD28 positive T cell responses and immune responses mediated by T cells.

It is noted that U.S. Patent No. 5,580,756 has priority back USSN 07/498949, filed March 26, 1990.

Applicant has argued that the invention is anticipated only if all elements of the claimed invention are present in a product or process discloses expressly or inherently in a single prior reference.

Applicant has acknowledged that Linsley et al. teach using B7 to regulate CD28 positive T cell responses and immune responses mediated by T cells.

However, applicant has argued that Linsley et al. does not describe or suggest that B7 is a ligand for CTLA4 receptor nor methods to regulate CTLA4 positive T cell responses.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Therefore, methods comprising the administration of B7 in vivo to regulate CD28 positive T cell responses and immune responses mediated by T cells, as acknowledged by applicant, must have the inherent property of regulating CTLA4 positive T cell responses. T cell express both CD28 and CTLA4.

When a claim recites using an old composition or structure (e.g. B7) and the use is directed to a result or property of that composition or structure (regulating CD28 positive / CTLA4 positive T cell responses and immune responses mediated by T cells), then the claim is anticipated. See MPEP 2112.02.

The claim language of inhibiting CTLA4 positive T cell responses is only a statement of purpose and intended result. The expression of inhibiting CTLA4 positive T cell responses does not result in a manipulative difference in the steps of the claims, wherein B7 is administered in vivo to regulate T cell and/or immune responses.

Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgram, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Co. v. Ben Venue Laboratories Inc. 58 USPQ2d 1508 (CAFC 2001).

See MPEP 2112-2112.02

Applicant's arguments have not been found persuasive.

7. Claims 38, 40 and 43-45 are rejected under 35 U.S.C. § 102(f) because the applicants did not invent the claimed subject matter.

As noted previously and above; in view of applicant's Petition to Correct Inventorship Under 37 CFR 1.48(b)(c), filed 6/18/00; the inventorship in this nonprovisional application has been changed by the deletion of Philip Wallace and Nitin Damle and by the addition of Robert Peach and Jurgen Bajorath have been added.

The current inventors include Linsley, Ledbetter, Bajorath, Peach and Brady.

Therefore, applicant's Petition to Correct Inventorship Under 37 CFR 1.48(b), filed 9/30/02, reiterates that the inventorship in this nonprovisional application has been changed by the deletion of Philip Wallace.

Now, applicant's amendment, filed 9/20/02 (Paper No. 20), asserts that Linsley, Ledbetter, Damle and Brady are the inventors of the pending claims.

However, Damle has been deleted previously as an inventor.

Bajorath and Peach have been added as inventors.

Therefore, applicant has created an ambiguity as to the inventorship of the instant claims.

Because of this ambiguity, it is incumbent on applicants to provide a satisfactory showing which would lead to a reasonable conclusion which applicants are the inventors of the claimed invention in view of applicant's Petitions to Change Inventorship of record and assertions.


8. No claim allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.


Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
March 3, 2003